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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,244	09/17/2001	David S. Goldsteen	293/002DIV2	1651
1473	7590	11/16/2004	EXAMINER	
FISH & NEAVE LLP 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105			THALER, MICHAEL H	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 11/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,244	GOLDSTEEN ET AL.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-27 is/are pending in the application.
- 4a) Of the above claim(s) 2-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 14-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 27, 2004 has been entered.

Claims 2-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 5.

Claims 1, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilk (5,429,144). Wilk discloses elongated guide structure 20 and longitudinal structure (e.g. the drill described in col. 6, lines 8-13, the needle 48 or the wire 60), a distal portion of the longitudinal structure adapted to penetrate the side wall of the organ, wherein both the elongated guide structure 20 and longitudinal structure are deflectable toward the side wall (e.g. figures 3B-D, 5A-C or 6A-C). As to claim 15, the distal portion of the longitudinal structure is resiliently biased to deflect laterally toward the side wall (by the curvature of the guide structure 20) when released from

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guidance by the guide structure. This is the case since the distal portion of the longitudinal structure, when released from guidance by the guide structure, is deflected laterally by the interaction of the guide structure 20 urging a more proximal portion of the longitudinal structure (i.e. a portion of the longitudinal structure that is still within the guide structure 20) laterally. As to claim 16, Wilk discloses a central longitudinal member 60 and a tubular member (one of the dilating catheters 62).

Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,429,144) in view of Yoon et al. (5,800,394). Wilk fails to disclose the distal portion of the longitudinal structure 14 (claim 14) or the tubular member 62 (claim 17) as being externally threaded. However, Yoon et al. teach that a penetrating member P of a tissue penetrating device should have external threads apparently so that it can obtain the advantage of more effectively penetrating tissue (col. 18, lines 1619. It would have been obvious to include external threads on the Wilk structure (14 or 62) so that it too would have this advantage.

Claims 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,429,144). Wilk fails to disclose balloons on the guide structure. However, it is old and well

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known in this art to provide balloons on tubular guide catheters and other members in order to obtain the advantages of steering the tip and holding the catheter in place in the body. It would have been obvious to include balloons on the Wilk guide structure 20 so that it too would have this advantage.


Applicant's arguments with respect to claims 1 and 14-27 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (703)308-2154. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
11/12/04


MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731